

Evaluating the effectiveness of acupuncture in defined aspects of stroke recovery.

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/01/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPGS816

Study information

Scientific Title

Study objectives

Acupuncture in addition to conventional treatment will have a greater effect on recovery from stroke than intervention by a placebo/control.

Background: Acute stroke counts for 12% of all death in Britain and an expected incidence of 500 per 250000 head of population, 40% of which will be admitted to hospital.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cerebrovascular disease

Interventions

Both groups will receive rehabilitative care and one of two treatment groups.

1. Acupuncture treatment will consist of dry needling to 3 out of 4 points in the upper limb chosen from; LI4, LI10, SJ5, LI15 with GB20 and 4 out of 5 in the lower limb GB43, BG39, GB34, GB30, ST36. Scalp acupuncture will also be used. The scalp over the motor cortex being stimulated with dry needles to which a direct current of high frequency is applied. Treatment will last 40 minutes and be given 3 times a week for 4 weeks.

2. The control group will receive a mock transcutaneous electrical nerve stimulation (TENS) treatment with adhesive electrodes applied to the same points as in 1. The TENS machine will be adjusted at the output jack so no current flows but it will still retain visual signs of function. Standard physiotherapy will be given to both groups, receiving treatment 5 times a week sometimes twice a day.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Motricity Index
2. Nottingham Health Profile
3. Standard Barthel Index

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/01/1997

Completion date

31/12/2001

Eligibility**Key inclusion criteria**

Patients who have recently suffered a stroke.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

105 patients randomised (5 centres) (added 26/01/10; see publication

Key exclusion criteria

1. History of previous stroke
2. Computed Tomography (CT) scan showing haemorrhage
3. Stroke without limb weakness
4. Unable to co-operate with treatments
5. Initial coma
6. Pacemaker
7. Significant co-morbidity

Date of first enrolment

02/01/1997

Date of final enrolment

31/12/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

School of Medicine

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2008		Yes	No